K073456

510(k) SUMMARY

DEC 2 0 2007

Submitted by:	MEDX, Incorporated 3456 N. Ridge Ave., #100 Arlington Heights, IL 60004
Telephone:	(847)-463-2020
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Contact Person	Floyd R. Rowan, Executive Vice President
Date Summary Prepared:	November 9, 2007
Trade Name of Device	T-Quest™ System
Common Name	Scintillation (Gamma) Camera System.
Classification Name:	Scintillation (Gamma) Camera
Classification:	This Device is Classified as a Class I Device. Ref. 21 CFR 892.1100. Product Code IYX.
Substantial Equivalence:	The T-Quest™ System is Substantially Equivalent to the Inter Medical Gamma Camera System Model CX 250 C Plus. 510(k) Number K052473.

Description of Device: The T-Quest System consists of a small mobile scintillation camera, accessories such as optional phantoms, and an optional patient bed. This product includes a notebook computer, an acquisition board, and IM512P Data and Image processor software marketed by MEDX, Inc. under the trade name of NuQuest™ Software. This system is primarily used for the acquisition, processing, and analysis of planar images of the thyroid gland and other small organs.

Scientific Concepts: Diagnostic Nuclear Medicine began in early 1950's with the availability of short half-life radioisotopes. Isotopes such I 131 were administered to the patient and were selectively taken up by organ systems such as the thyroid. Measurement of the resulting radioactivity in the organ provided information on both the size of the organ and the relative amount of the isotope taken up.

Nuclear Medicine cameras work on the principle similar to television cameras. A collimator (lens) "focuses" gamma rays on a scintillation crystal. The scintillation crystal converts the gamma rays into light. Photomultiplier tubes are then used to convert the light into an electrical signal proportional to the energy of the detected gamma ray. Early instruments used a single hole lead collimator and detector moved in a raster pattern forming a 2-D image of the organ of interest. In the late 1950's methods were developed for directly obtaining a 2-D image by using a large crystal with multiple photomultiplier tubes and electronically calculating the position and energy of the gamma event. As computers became available the resulting images were portrayed on computer screens.

Indication for Use: The intended uses of the T-Quest™ System are the acquisition, processing, display and analysis of planar images of the thyroid gland and other small organs using approved pharmaceuticals.

Note: The predicate device in its indication for use does not include the word "analysis", this refers to the analysis of energy levels. It the physician who interprets the data and makes the clinical decisions, not the gamma camera system.

Safety Information:	The T-Quest™ System Meets UL 60601-1 and CAN/CSA C22.2 No. 601-1 Standards and is In Compliance with EMI Standards.
Performance Standard:	This Device Meets NEMA NU 1-2001 Standard for Uniformity, Linearity, and Resolution.

Non-Clinical Data: The T-Quest™ System performance characteristics with respect to Linearity, Resolution, Uniformity, and of the thyroid gland phantom

images were deemed to be excellent. The conclusion drawn from this data is that the T-Quest™ System provides effective results as expected from similar devices in the marketplace..

Device Technological Characteristics: The characteristics of the T-Quest™ Scintillation Camera when used with the NuQuest™ computer and NuQuest™ (IM512P) Software compare substantially with the predicate device, in both materials used, technology applied, and functional methodology. Differences of note do not affect safety and effectiveness of the device, intended use, or application methods. The device operates in a manner substantially equivalent to other cleared devices in this category, and performs as well as the predicate device.

COMPARISON OF T-Quest™ SYSTEM TO PREDICATE DEVICE

	T-Quest System	Inter Medical CX250C 510(k); K052473
Indication for Use	The intended uses are the acquisition, processing, display and analysis of planar images of the thyroid gland and other small organs using approved pharmaceuticals.	The CX250^{Plus} Gamma Camera is a mobile system for acquisition and processing nuclear medicine diagnostic. Note: this camera also displays the planar images and requires the use of approved pharmaceuticals.
Compact Mobile Gamma camera for acquisition, processing representation and documentation of patient isotope studies.	Yes, but only for small organs such as the thyroid.	Yes, for both small and large organs.
Thyroid Collimator	Yes	Yes
Iodine 131 Studies	No	Yes
Iodine 123 Studies	Yes	Yes
Technetium 99m Studies	Yes	Yes
DICOM Data Transfer Capability	Yes	Yes
Adjustable Head	Yes	Yes
Pinhole Collimator	Yes	Yes

General Purpose Collimator	Yes	Yes
Computer	External Notebook PC Providing the Keyboard and Viewing Screen.	Built-in Computer with external Keyboard and Viewing Screen.
Operating System	Windows XP	Windows XP
Display	Color or Grayscale	Color or Grayscale
Number of Photomultiplier Tubes	19	19 or 37
Corrections	Linearity, Energy, and Uniformity	SAME
Acquisition Matrixes	64x64, 128x128, 256x256, 512x512, and 1024x1024.	64x64,128x12, 256x256. and 512x512
Frame Mode	Static, Dynamic, and Gated.	Static, Dynamic, and Gated.
Patient Archive	CD/DVD	CD/DVD, PLUS Magneto Optical Drive is Available
Acquisition Board	Nuquest™ Acquisition Board is Located Below the Shelf that Holds the Notebook PC.	Proprietary electronics performing the same function.
Software	Uses previously 510(k) Cleared Software Called IM512P which is Marketed by MEDX, INC under the trade name of NuQuest™ Software. This software was cleared in the following 510(k)'s for FDA Code IYX Products: K945792 and K961104	Gamma XP Acquisition and Processing Software. Its previous history is unknown to us.

EXPLANATIONS PERTAINING TO 510(K) NUMBERS PROVIDED IN THE COMPARISSON TABLE ABOVE.

K052473 is the FDA cleared 510(k) for the model CX250C Plus Gamma Camera System manufactured by Inter Medical. This is the predicate device to which we are comparing our T-Quest System.

K945792 is the FDA cleared 510(k) for IM512P software filed by Globus Industries which is the U.S. Agent for Alfanuclear S.A. I. y C. in Buenos Aires Argentina which designs and markets the IM512P software.

K961104 is the FDA cleared 510(k) for Notebook Imager a product of Digirad Corp. This device uses IM512P software cleared Sitco 510(k) K945792 which is now owned by MEDX, Inc.

The purpose of discussing the 510(k)'s (other than K052473) is to demonstrate that the Alfanuclear IM512P software has been in use for over 12 years, that it has been cleared by the FDA and that is not a new technology for acquisition and imaging of scintillation (gamma) camera images .

DISCUSSION OF THE DIFFERENCES LISTED IN THE COMPARISSON OF T-QUEST SYSTEM TO THE INTER MEDICAL PREDICATE DEVICE.

The T-Quest System is a smaller gamma camera system as is observed that it uses only 19 Photomultiplier tubes (PMT)s whereas the Inter Medical Device uses both 19 and 37 PMTs. For thyroid and other small organ imaging the 19 PMT detector heads are used by us and the predicate device.

As for acquisition matrixes, which define the resolution of the images, the 1024x1024 mode can be used but it is impractical for thyroid imaging because it takes a longer time to acquire the image and requires large amount of storage memory.

Patient Archives - we do not view the use of Magneto Optical Storage Devices as a detraction from our system which does not use them. The CD and DVD data storage methods are widely used and preferred by users of gamma camera systems

Iodine 131 Studies the T-Quest System would require a greater level of lead shielding to handle this isotope. The Technetium 99m and Iodine 123 provide very usable thyroid images.

Overall both systems are substantially equivalent in the acquisition, processing, display and analysis of planar images of the thyroid and other small organs using approved pharmaceuticals.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2007

MEDX, Inc.
% Mr. Jeff D. Rongero
Senior Project Engineer, Medical Business Unit
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709

Re: K073456
Trade/Device Name: T-Quest™ System
Regulation Number: 21 CFR 892.1100
Regulation Name: Scintillation (gamma) camera
Regulatory Class: I
Product Code: IYX
Dated: November 30, 2007
Received: December 10, 2007

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073456

Device Name: T-Quest™ System

Indications For Use:

The intended uses of the T-Quest™ System are the acquisition, processing, display and analysis of planar images of the thyroid gland and other small organs using approved pharmaceuticals.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K073456